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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,022	02/09/2004	Ramez Emile Nicola Shehada	064693-0101	9082

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EXAMINER
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HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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10/776022

EXAMINER
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ART UNIT	PAPER
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20060505

DATE MAILED:

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**Commissioner for Patents**

**Office Action Summary**

Application No.

10/776,022

Applicant(s)

NECOLA SHEHADA ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-16 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/24/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restriction***

1. It is noted that Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 April 2006.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1-4 and 9-16 under Johnson (US 3,866,599); claims 5-8 under Johnson in view of Russo et al. (US 4,317,452); claim 6 over Johnson in view of Harutuneian (US 3,989,571), Koehn (US 3,030,953), Santomieri (US 3,515,137), and Beck (US 3,537,451); claim 7 over Johnson in view of Sadowski (US 3,614,737); and claim 8 over Johnson in view of Sadowski in view of Leist (US 4,432,365) have been considered but are moot in view of the new ground(s) of rejection as discussed below.

### ***Claim Amendment Objection***

The format of the amendments to the claims is objected to because this document should only contain a listing of all claims with their corresponding identifiers. The status of the claims at the top of the page should go in the 'Remarks' document in compliance with the amendment format rules as per 37 CFR 1.121.

***Specification***

3. The objections to the specification have been removed upon Applicant's amendments.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of the 'elongated conduit configured to be implanted in a patient's body and rest against a first tissue and a second tissue within the body' as recited in lines 3-4 of claim 1 is supported by figure 9 only when the first tissue and second tissue are part of the same organ (see claim 21). Although there is support in the specification for the first tissue and second tissue to be not part of the same organ (see page 16, paragraph 0074), there is no support for the combination of conduit resting against the first and second tissue when the tissues are not part of the same organ as recited in newly added claim 22.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 7-16 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skrabal (US 5,097,834; herein 'Skrabal') in view of Goodman et al. (US 4,938,218; herein 'Goodman'). Regarding claims 1-4, 8, 10-16 and 21-22 Skrabal discloses a surgical drain 5 for sensing a physiological property of tissue and draining fluid from a body (column 9, lines 13-17 and lines 23-25, column 6, lines 44-55) comprising: (a) an elongate conduit/catheter 2 configured to be inserted into the tissue (column 9, lines 10-12, column 11, lines 59-63) to drain fluid from the patient's body wherein the drain portion has openings spaced along the length of the wall (column 2, lines 34-40, column 9, lines 21-22 and figure 1); and negative pressure sensor 18 located in the tubes 7, 7' of implanted catheter 2 (column 10, lines 41-45). Skrabal *does not expressly disclose* multiple sensors for sensing various physiological properties. **Goodman** discloses measurement of blood-oxygen has been accomplished by use of a non-invasive sensor which passes two sets of light sources/energy delivering means through a portion of the patient's tissue and photoelectrically senses the absorption of light in the tissue (column 1, lines 24-38 and column 2, lines 5-6). Goodman further discloses the probe may further be provided with optics, an ECG electrode, and further sensors to measure temperature and perfusion of blood in the fetal tissue (column 4, line 59-column 5, line 2). Goodman also discloses vent tube 136 in which fluids and solid matter are drawn into/drained into vacuum tube 134 from the body cavity 106 (column 7, lines 48-51). One would be motivated to modify the apparatus of Skrabal with the multiple sensors resting against the tissue of Goodman for sensing physiological data for a non-invasive way to monitor tissues since the references

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disclose sensing devices with drains implantable into the body. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the draining apparatus and thus providing multiple sensors resting against the tissues.

Regarding claims 7 and 9 Skrabal further discloses calibrating unit/processing system 20 (column 9, lines 59-64) and computer of evaluation unit 11, which inherently has a display to output data collected and computed by the computer (column 9, lines 40-43).

Regarding claim 23 Skrabal/Goodman do not expressly disclose the sensors are on the same surface of the conduit. It would be obvious to one of ordinary skill in the art at the time the invention was made to place the sensors in any location relative to the tissue location so that the sensors may gather information from the tissues by being close in proximity. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the sensors, thus providing them on the same surface.

Regarding claim 24 Goodman further discloses sensor 802 on the opposite side of fetal ECG electrode 806 (column 13, lines 20-23 and figures 8a and 8b).

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skrabal (US 5,097,834; herein 'Skrabal') in view of Goodman et al. (US 4,938,218; herein 'Goodman') as applied to claim 1, and further in view of Koehn (US 3,030,953), Santomieri (US 3,515,137) and Beck (US 3,537,451). Regarding claim 6 Skrabal discloses the sensing element 18' is embedded within the inserted conduit 2 (column 10, lines 41-42 and figure 1). Skrabal/Goodman *do not expressly disclose* the sensing

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elements are embedded within a material that is optically transparent. It is well known to use transparent polyvinylchloride, polyethylene, polytetrafluoroethylene (also known as Teflon®), and polyurethane materials for catheters as taught by Harautuneian, Koehn, Santomieri and Beck. One would be motivated to modify the catheter material of Skrabal/Goodman with the optically transparent catheter materials of Harautuneian, Koehn, Santomieri and Beck to provide a means to visually inspect the sensing elements through the conduit during use. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter material, thus providing an optically transparent material.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lange et al. (US 6,751,499) is cited for showing a physiological monitoring system 100 comprising components for measuring blood pressure, pulse, temperature, respiration and pain level that contact the skin surface/rest against a tissue; a set of electrodes 12 on a sensor array having a color-coded strip which processes a pain signal using analog circuitry and presents the pain result as a specific color scale on a display in a discrete reading format based on four levels of pain; and an IV fluid container placed within the body cavity to apply fluid *into* the body.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill  
Examiner  
Art Unit 3761  
LCH



**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

